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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,988	12/28/2001	Ronald J. Pettis	500752999021	4336

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EXAMINER	
MENDEZ, MANUEL A	
ART UNIT	PAPER NUMBER
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/028,988	PETTIS ET AL.	
	Examiner	Art Unit	
	Manuel Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-34,36-52 and 67-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-34,36-52 and 67-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____:

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *December 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Rejection No. 1

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-52 and 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross in view of PURI (An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems) or D'Antonio, et al., (US Patent No. 6,056,716) and in further view of Ganderton, et al., (U.S. Patent No. 3,814,097), and Autret, et al., (Therapie 1991; 46:5-8)**. If the claimed method of intradermal delivery disclosed by Gross is not inherent, it would have been obvious to one of ordinary skill in the art to deliver drugs at particular pressures and flow rates to achieve higher Cmax and AUC than subcutaneous injection. Puri and D'Antonio disclose that intradermal injections give much greater Cmax values than subcutaneous. The prior art disclosures suggest a greater Cmax and AUC. (see Puri, pgs. 2609-2610, and D'Antonio col. 29, lines 3-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Puri or D'Antonio in the method of Gross in order to more effectively treat patients and save drug costs.

Concerning the use of multiple needle apparatuses, Ganderton, et al., (U.S. Patent No. 3,814,097) discloses injecting a substance through multiple needles. Moreover, concerning the infusion of hormones into the body, Autret, et al., (Therapie 1991; 46:5-8) discloses the intradermal injection of a hormone that results in a pharmacokinetic profile similar to subcutaneous delivery. Based on the above observations, for a person of ordinary skill in the art, modifying the methods disclosed by Gross, PURI, and/or D'Antonio, et al., with the use of apparatuses having multiple needles and with the infusion of hormones would have been considered obvious in view of the conventionality of these enhancements.

Rejection No. 2

Claims 33-52 and 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross in view of PURI (An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems) or D'Antonio, et al., (US Patent No. 6,056,716), Ganderton, et al., (U.S. Patent No. 3,814,097), or Autret, et al., (Therapie 1991; 46:5-8), as discussed above, and in further view of Eriksson, Palasis, et al., Prausnitz, et al., Rosenberg, Lastovich, et al., Hjertman, Carson et al., Kling, Son, or Riethmueller.**

The Ericksson and Palasis, et al., patents do not expressly disclose a microneedle having the range of 31 to 50 gauge, or a bevel angle between 20 and 90 degrees. However, the use of microneedles having the above-cited ranges is conventional in the art as evidenced by the Prausnitz, et al., Rosenberg, and Lastovich patents.

The Prausnitz, et al., patent discloses a microneedle infusion system utilizing microneedles with a 30 gauge. Moreover, Rosenberg discloses a transdermal delivery device having microneedles with a 15 to 40 gauge. Finally, the Lastovich, et al., patent discloses another infusion system having microneedles with bevel angles of 15 to 35 degrees.

Based on the teachings of Prausnitz, et al., Rosenberg, and Lastovich, et al., and the proven conventionality of the above enhancements, for a person of ordinary skill in the art, the modification of the infusion systems disclosed by Eriksson and Palasis, et al., with microneedles having the range of 31 to 50 gauge, or a bevel angles between 20 and 90 degrees, would have been considered obvious design choices.

Finally, in relation to the use of limiters surrounding needles, it is important to recognize that such limiters are conventional in the art as evidenced by the teachings of **Hjertman, Carson et al., Kling, Son, and Riethmueller. These patents demonstrate that the use of limiters to surround needles and to selectively ensure a particular depth of infusion, are concepts well known in the art of needles.**

Accordingly, for a person of ordinary skill in the art, modifying the apparatuses disclosed by Eriksson or Palasis, et al. with a limiter that surrounds a needle and a skin engaging surface, would have been considered obvious in view of the proven conventionality of these enhancements, and furthermore, because of the resulting and improved safety standards of the infusion needles.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Manuel Mendez
Primary Examiner
Art Unit 3763

MM